

K120686

Codman & Shurtleff, Inc.

Special 510(k)
ORBIT GALAXY® G2 Microcoil System**510(k) Summary**

(As Required By 21 CFR 807.92(a))

APR - 4 2012

A. Submitter Information

Submitter's name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
 Raynham, MA 02767
Telephone: 408-433-1420
Fax: 408-433-1585
Contact Person: Kim Fonda
Date of Submission: March 5, 2012

B. Trade/Device Name: ORBIT GALAXY® G2 Microcoil Delivery System
Common Name: Artificial embolization device
Classification Name: Neurovascular Embolization Device
Regulation Number: Class II per 21 CFR 882.5950

C. Predicate Devices:

Device	Company	510(k) Number/ Concurrence Date	Product Code	Predicate For:
Micrus Microcoil System, CASHMERE® SR (Primary predicate)	Codman & Shurtleff, Inc (Previously Micrus Endovascular Corp.)	K072173 (10/5/2007)	HCG	Intended Use Design Materials Manufacturing Sterilization
ORBIT GALAXY® Detachable Coil System	Codman & Shurtleff, Inc	K093973 (5/26/2010)	HCG	Intended Use Design Materials Manufacturing

D. Device Description:

The intent of endovascular treatment using embolic microcoils is to pack the lumen of the aneurysm with the microcoil mass, thereby eliminating the influx of blood into the aneurysm. The aneurysm neck will be covered with loops of coils to help eliminate the influx of blood, a blood flow pathway is then re-established down the lumen of the parent artery, and the weakened wall of the aneurysm is isolated from arterial pressures. The existing blood and soft clot trapped within the lumen of the aneurysm begins to solidify, ultimately becoming hardened clot and scar tissue. The process will re-establish blood flow down the lumen of the parent artery and thromboses the aneurysm.

The ORBIT GALAXY® G2 Microcoil Delivery System consists of a Microcoil System, a Connecting Cable (CC), and an ENPOWER Detachment Control Box (DCB). Each component is sold separately. ORBIT GALAXY® G2 Microcoil Systems are provided as Stretch Resistant, with Fill and XTRASOFT™ microcoil models, and will be offered in lengths ranging from 1.5 cm to 30 cm and diameters ranging from 2 mm to 20 mm. The ORBIT GALAXY® G2 Microcoil System is compatible with commercially available 2-tip marker microcatheters which have internal lumen diameters between 0.0165 inches and 0.019 inches.

The Microcoil System consists of an embolic microcoil attached to a device positioning unit (DPU) which is covered by an introducer sheath. The Fill ORBIT GALAXY® G2 Microcoils are provided in complex shape, and the XTRASOFT™ ORBIT GALAXY® G2 Microcoils are provided in complex and helical shapes. The DPU is a variable stiffness pushing system and has a radiopaque marker band located three (3) cm from its distal end. The introducer sheath system has three main components: an introducer tip, a translucent introducer body, and a re-sheathing tool. The Microcoil System is packaged individually in a protective hoop and sealed in a film pouch. A Microcoil System carton contains one Microcoil System and the associated Instructions for Use, and is provided as a sterile and single-use product.

The Connecting Cable delivers the energy needed to detach the microcoil from the Microcoil System's detachment zone. The connecting cable connects the DPU to the DCB. The DCB provides the energy necessary to allow for a thermo-mechanical detachment of the microcoil from the DPU.

The ORBIT GALAXY® G2 Microcoil System is a modification to the currently marketed CASHMERE® SR Microcoil System (K072173), and to the ORBIT GALAXY® Detachable Coil System (K093973). The ORBIT GALAXY® G2 Microcoil System uses the same Device Positioning Unit, Introducer Sheath System, Detachment Control Box, and Connecting Cable components as the CASHMERE® SR Microcoil System (predicate device). The ORBIT GALAXY® G2 System offers a microcoil similar to the CASHMERE® SR and ORBIT GALAXY® Microcoils (predicate devices). The ORBIT GALAXY® G2 microcoil is similar to the CASHMERE® SR predicate device in regards to microcoil size, material, monofilament suture used for stretch resistance, primary wind profile, secondary shape, outer diameter and length. Device modifications include design and manufacturing process changes necessary to expand the product line to include additional microcoil shapes and sizes.

E. Intended Use:

The Fill ORBIT GALAXY® G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The XTRASOFT™ ORBIT GALAXY® G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

F. Summary of technological characteristics of the proposed to the predicate device:

The ORBIT GALAXY® G2 Microcoil Delivery System is similar to the CASHMERE® SR Microcoil System with regard to intended use, function, design, materials, manufacturing, and sterilization processes.

The ORBIT GALAXY® G2 Microcoil Delivery System is similar to the ORBIT GALAXY® Detachable Coil System with regard to the intended use, function, microcoil material, shape and dimensions, and microcoil manufacturing processes.

Device modifications include design and manufacturing process changes necessary to expand the product line to include additional microcoil shapes and sizes. No new technological characteristics are being introduced with the proposed device.

A summary table including specifications of the proposed device compared with those of the predicate devices follows.

Comparative Information			
Characteristic	Proposed Device G2 System	Predicate Device CASHMERE SR System	Predicate Device GALAXY System
Intended Use	<p>The Fill ORBIT GALAXY G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.</p> <p>The XTRASOFT ORBIT GALAXY G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms</p>	<p>The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature. <i>As modified per premarket notification K073442 (2/26/08)</i></p> <p><u>K072173 (10/5/07)</u> The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.</p>	<p>The Fill ORBIT GALAXY Detachable Coil and the Frame ORBIT GALAXY Detachable Coil are indicated for embolizing intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.</p> <p>The Fill ORBIT GALAXY Detachable Coil and the Frame ORBIT GALAXY Detachable Coil are also intended for arterial and venous embolization in the peripheral vasculature.</p> <p>The XTRASOFT ORBIT GALAXY Detachable Coil is indicated for embolizing intracranial aneurysms</p>

Comparative Information			
Characteristic	Proposed Device G2 System	Predicate Device CASHMERE SR System	Predicate Device GALAXY System
Microcoil Characteristics			
Configurations	XTRASOFT Stretch Resistant and Fill Stretch Resistant Platinum Tungsten Alloy Wire	Complex Stretch resistant Platinum Tungsten Alloy Wire	XTRASOFT Stretch Resistant and Fill Stretch Resistant Platinum Tungsten Alloy Wire
Embollic Microcoil material			
Internal suture material	Polypropylene	Polypropylene	Polypropylene
Primary Coil Wind OD	0.012 inches	0.0135 inches	0.012 inches
Profile of Primary Coil Wind	Cylindrical	Cylindrical	Cylindrical
Secondary shape	Fills -Complex XTRASOFT -Complex and Helical	Complex	Fills -Complex XTRASOFT -Complex and Helical
Secondary Shape Coil OD	2-20 mm	2-12 mm	2 - 20 mm
Coil length	1.5 - 30 cm	2.5 - 30cm	1.5 - 30 cm
System Characteristics			
Delivery System Type	Wire shaft with radiopaque markers.	Wire shaft with radiopaque markers.	Hypotube welded to support coil with welded in-line marker bands
Delivery System Introducer Sheath	HDPE Introducer	HDPE Introducer	Nylon/HDPE Introducer
Delivery System Resheathing tool	Nylon 12	Nylon 12	HDPE

Comparative Information			
Characteristic	Proposed Device G2 System	Predicate Device CASHMERE SR System	Predicate Device GALAXY System
DPU Delivery System Length	190 cm (185-195cm)	190 cm (185-195cm)	155 – 210 cm
Microcatheter compatibility	Compatible with 2-tip marker microcatheters of ID from 0.0165 to 0.019 inches	Compatible with 2-tip marker microcatheters of ID from 0.0165 to 0.019 inches	Compatible with 0.014” or 0.018” guidewire compatible infusion catheter, 150 cm long, dual marker band
Detachment Mechanism	Connection to Microcoil System: Uses Connecting Cable	Connection to Microcoil System: Uses Connecting Cable	Hydraulic Detachment System uses TRUFILL DCS Syringe II
	Detachment: Thermo-mechanical System uses ENPOWER Detachment Control Box (DCB) with ENPOWER Control Cable	Detachment: Thermo-mechanical System uses ENPOWER Detachment Control Box (DCB) with ENPOWER Control Cable	
Sterilization	E-Beam Radiation	E-Beam Radiation	ETO
Packaging	Packaged in a plastic hoop and enclosed in a sealed LD Polyethylene/Polyester film pouch.	Packaged in a plastic hoop and enclosed in a sealed LD Polyethylene/Polyester pouch.	Packaged in a plastic hoop and enclosed in a sealed Nylon/Tyvek pouch.

G. Testing Summary:

Bench testing data demonstrated that the ORBIT GALAXY® G2 Microcoil System performed according to its description and intended use, and established the performance characteristics of this device. The ORBIT GALAXY® G2 Microcoil System passed equivalent bench testing as compared to the CASHMERE® SR System predicate device. Clinical testing was not required to establish substantial equivalence.

Results of verification and validation testing conducted on the ORBIT GALAXY G2 Microcoil System demonstrated that the system performed as designed, is suitable for the intended use, and is substantially equivalent to the predicate devices.

The following tests were conducted to verify the modified design:

- Delivery Force Test
 - System Delivery Force
 - Microcatheter compatibility
- Secondary Shape Retention Test
 - Coil Secondary Shape OD
- Detachment Zone Tensile Test
 - Coil Socket Ring Tensile Strength
 - Detachment Suture Tensile Strength
 - Stretch resistance of suture/Tensile Strength
 - Ball Tip Tensile Strength
- Durability and Detachability Test
 - Durability-Cyclic advancement and retrieval of the microcoil system
 - Detachment of the microcoil from the delivery system
 - Coil damage after microcoil system delivery
 - Microcatheter compatibility

The materials, packaging, and sterilization used in the ORBIT GALAXY® G2 Microcoil Delivery System are identical to the materials, packaging, and sterilization used in the current CASHMERE SR Microcoil System. Full biocompatibility testing in accordance with ISO 10993-1 was previously successfully conducted on the ORBIT GALAXY® Detachable Coil System (K093973); additional biocompatibility testing was performed on the CASHMERE SR System (K072173).

For final confirmation biocompatibility screening testing was successfully performed. Results demonstrated that the ORBIT GALAXY® G2 Microcoil Delivery System meets all the same biocompatibility requirements as the predicate devices and as specified by the ISO 10993 Part I, and the General Program Memorandum # G95-1 on Biological Evaluation of Medical Devices.

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Codman & Shurtleff, Inc., it is concluded that the ORBIT GALAXY® G2 Microcoil Delivery System is substantially equivalent to the CASHMERE® Microcoil Delivery System and to the ORBIT GALAXY® Detachable Coil System and, therefore, does not raise any new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Codman & Shurtleff, Inc.
% Ms. Kim Fonda
325 Paramount Drive
Raynham, MA 02767

APR - 4 2012

Re: K120686

Trade/Device Name: Orbit Galaxy® G2 Microcoil Delivery System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: March 5, 2012
Received: March 6, 2012

Dear Ms. Fonda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical


device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120686

Device Name: Orbit Galaxy® G2 Microcoil Delivery System

Indications for Use:

The Fill Orbit Galaxy® G2 Microdelivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is intended for arterial and venous embolizations in the peripheral vasculature.

The Xtrasoft Orbit Galaxy® G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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